

**The Department of Health and Human Services  
Meeting of the  
Secretary's Advisory Committee on Human Research Protections (SACHRP)  
Wednesday, July 10, 2013 – Thursday, July 11, 2013  
Hubert H. Humphrey Building, Room 800  
AGENDA**

**Wednesday, July 10, 2013**

8:30 a.m. – 8:45 a.m.

**Welcome: Opening Remarks**

Jeffrey R. Botkin, M.D.  
SACHRP Chair

Jerry Menikoff, M.D., J.D.  
Director, OHRP

8:45 a.m.- 9:15 a.m.

**Welcome and Remarks**

Howard Koh, M.D., M.P.H.  
Assistant Secretary for Health  
U.S. Department of Health and Human Services

9:15 a.m.- 10:15 a.m.

**Subcommittee on Harmonization (SOH)**

David Forster, J.D., M.A., C.I.P., SOH Co-chair  
Mark Barnes, J.D., SOH Co-chair

10:15 a.m.- 10:30 a.m.

**BREAK**

10:30 a.m. – 11:30 a.m.

**Clustered Randomized Trials and Informed Consent**

David Forster, J.D., M.A., C.I.P., SOH Co-chair

Bernard Lo, M.D.  
President  
The Greenwall Foundation  
Professor of Medicine Emeritus  
Director Emeritus, Program in Medical Ethics  
University of California San Francisco

Charles Weijer, M.D., Ph.D.  
Professor of Philosophy and Medicine  
Canada Research Chair in Bioethics  
Western University, London, Canada

Monica Taljaard, Ph.D.  
Scientist, Ottawa Hospital Research Institute  
Clinical Epidemiology Program  
Assistant Professor, University of Ottawa

11:30 a.m.- 1:00 p.m.

**CRT Discussion**

1:00 p.m. – 2:00 p.m.

**LUNCH**

2:00 p.m.- 3:00 p.m.

**Certificates of Confidentiality**

David Forster, J.D., M.A., C.I.P., SOH Co-chair

Ann Hardy, Dr. Ph.

NIH Extramural Human Research Protections Officer and  
Coordinator, Certificates of Confidentiality Program

Cheryl Crawford Watson, J.D.

Senior Advisor, Human Subjects Protection Officer  
Office of the Director

National Institute of Justice

Office of Justice Programs

U.S. Department of Justice

3:00 p.m. – 3:45 p.m.

**COC Discussion**

3:45 p.m. – 4:15 p.m.

**SACHRP Future Directions**

4:15 p.m. – 4:30 p.m.

**Public Comment**

4:30 p.m.- 4:45 p.m.

**Wrap-up Discussion and Adjourn**

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8:30 a.m. – 8:45 a.m.

**Opening Remarks**

Jeffrey Botkin, M.D.  
SACHRP Chair

Jerry Menikoff, M.D., J.D.,  
Director, OHRP

8:45 a.m.- 10:30 a.m.

**Subpart A Subcommittee (SAS)**

Daniel K. Nelson, M.S., CIP, SAS Co-chair  
David Borasky, M.P.H., CIP, SAS Co-chair

**10:30 a.m. – 11:00 a.m.**

**BREAK**

11:00 a.m.- 12:15 p.m.

**Subpart A Subcommittee (SAS)**

Continued

12:15 p.m.- 1:15 p.m.

**LUNCH**

1:15 p.m. – 3:00 p.m.

**Electronic Informed Consent**

David Forster, J.D., M.A., C.I.P.  
Vice President, Office of Compliance  
Western Institutional Review Board

Anthony J. Costello, Ph.D  
Chief Executive Officer  
Mytrus

Justin McCarthy, J.D.  
Senior Vice President, Associate General Counsel  
Chief Counsel – Worldwide Research &  
Development  
Pfizer Inc.

Jeffrey Kahn, PhD, MPH  
Robert Henry Levi and Ryda Hecht Levi  
Professor of Bioethics and Public Policy  
Johns Hopkins University  
Berman Institute of Bioethics

3:00 p.m.- 3:15 p.m.

**Public Comment**

3:15 p.m. – 3:30 p.m.

**Wrap-up Discussion and Adjourn**